

EXHIBIT 83

DOCUMENT PRODUCED IN NATIVE FORMAT

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ABC Diversion Control Program effective June 25, 2007

**Corporate Security & Regulatory Affairs (CSRA) Dept.
AmerisourceBergen Corporation**



ABC's Responsibility Under the Law

- ▶ DEA expects distributors to conduct due diligence of customers to ensure controlled substances do not enter illicit channels
- ▶ According to DEA, a pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor.
- ▶ Thus, the DEA registration of the distributor could be revoked under public interest grounds.



ABC's Responsibility Under the Law

- **21 CFR 1301.74** requires that registrants design and operate systems to identify suspicious **orders** and report suspicious **orders** to DEA when discovered.
- ▶ Reporting suspicious orders to DEA does NOT relieve the distributor of the responsibility to maintain effective controls to prevent diversion.
- ▶ DEA cannot tell a distributor if an order is legitimate or not and usually will not tell the distributor whether or not to ship.
- ▶ Distributor must make a “business decision” whether or not to ship the order.



ABC's Diversion Control Program

- ▶ **“Know Your Customer” Due Diligence**
- ▶ **48-Hour reporting to DEA**
- ▶ **Order Monitoring Program (OMP)**
- ▶ **Investigations**
- ▶ **Education and Training**



New Customer Due Diligence

- ▶ “Know Your Customer”
- ▶ All New Alt Care, Retail and Wholesale Accounts
 - Retail Chain pharmacies exempted that have 10 or more locations or any number of locations in two or more states
 - **DEA has 13 classifications of “Business Activity” and the ones that describe our customers include; hospital/clinic, retail pharmacy, distributor, researcher, manufacturer, importer and exporter. Alternate Care accounts are normally registered by the DEA as a retail pharmacy.**



New Customer Due Diligence (cont.)

- ▶ Included in New Account Setup Process
 - CSRA I Form 590 Retail Pharmacy Questionnaire
 - On-site visit w/photographs inside and out (or physical description)

- ▶ Monthly Dosage Unit Sales Limits
 - All new accounts set at lowest threshold for DEA business type in ABC's new Order Monitoring Program (OMP)

- ▶ Do Not Ship List
 - Pharmacies ABC has ceased distribution due to suspicious activity
 - Other sources



48 – Hour Reporting

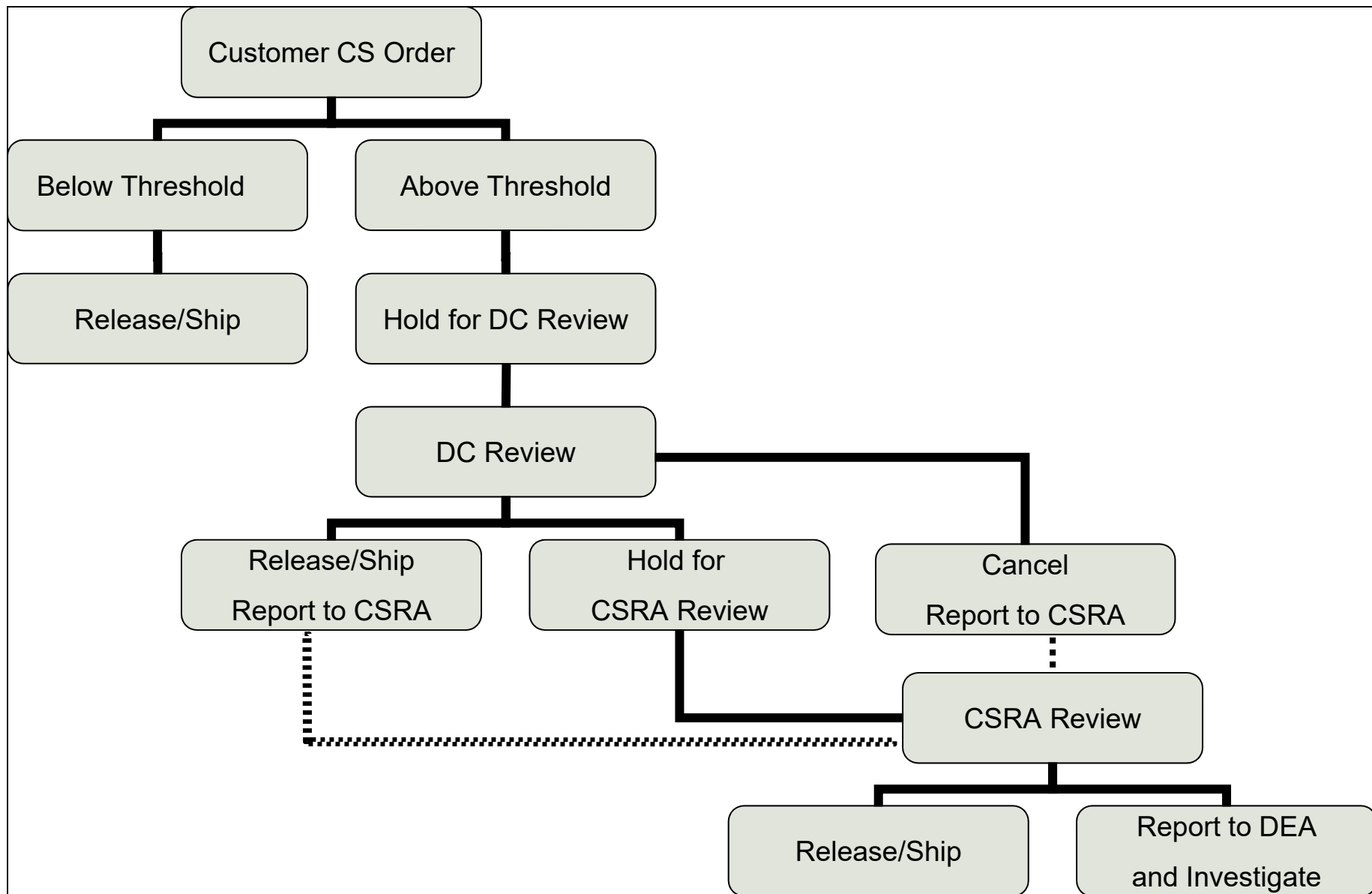
- ▶ Communication with DEA
 - All CS activity to be reported within two (2) business days





Order Monitoring Program (OMP)

- ▶ Order Monitoring Program
 - Controlled Substance and Listed Chemical Orders above established monthly thresholds held for DC review
 - DC Review by responsible associate – Cancel, Hold, or Release
 - Corporate Security & Regulatory Affairs (CSRA) review – Cancel, Hold, or Release
 - CSRA to investigate and report all held/cancelled suspicious orders to DEA





Order Monitoring Program (OMP)

- ▶ A new value called “DEA Customer Type” has been added to the MF Customer Master. This value represents how the customer is licensed with the DEA.
 - Hospital/Clinic, Retail Pharmacy, Distributor, etc.
- ▶ A new value called “OMP Customer Size” has been added to the MF Customer Master. This value represents the size of the customer relative to its peers in the DEA Customer Type group.
- ▶ A customer threshold will be accumulated on a monthly basis by item family.
 - The order quantity will be the basis for this accumulation.
 - The accumulation will be reset at the beginning of each month.



Order Monitoring Program (OMP)

- ▶ **Orders will be checked for items that belong to item families. Items within item families will be grouped together and their order quantity compared to the Item Family Threshold.**
- ▶ **If the order quantity falls below the Item Family Threshold, the order will process normally.**
- ▶ **If the order quantity goes over the Item Family Threshold, the order will be placed into a “OMP Review” screen. Subsequent orders within the same Item Family will be rejected while an item within the same Item Family is under review.**
- ▶ **The DC will be responsible for the initial review of the order. If the order quantity is not suspicious, the DC can release the order. If the DC is unsure, the order should be flagged to be investigated by CSRA.**
- ▶ **The AS400 EOD process will send the orders in “Investigate” status to the CSRA department each day. CSRA will determine if the order will be investigated and reported to the DEA.**



Order Monitoring Program (OMP)

▶ AS400 OMP Review

- A new review screen is being developed on the AS400 for the DC to use to monitor the OMP orders.
- Customer orders will go through the normal “hold” screen (credit hold, suspect quantity, etc.) processes. Once the order is released from hold, it will go to OMP Review.
- Once the order is released from OMP Review, it will process normally. C2 items will then be available for release on the C2 Order Release screen.

▶ Order Processing- IRMC Codes

- New IRMC codes have been added for the OMP process.
- Code “OQ” means that the order is in OMP Review. The quantity is not allocated and an allocated quantity will not be sent to the customer.
- Code “OC” means that the order is canceled because the customer is over their threshold.



Order Monitoring Program (OMP)

- ▶ ABC can't totally rely on systems and computer programs to prevent diversion.
- ▶ Each ABC Associate has a role and responsibilities in AmerisourceBergen's Order Monitoring Program
- ▶ It is each ABC Associate's specific responsibility to review and hold all orders of a suspicious nature, to report suspicious orders to your designated supervisor and to follow the instructions of your designated supervisor prior to releasing.



CSRA Investigations

▶ Sources of Investigations

- CS/LC Order Monitoring Program (OMP)
- Notification by DEA
- Notification by ABC DC
- Monthly Customer Product Mix Report

▶ Investigation Process

- One-year purchase history
- On-site inspection
- **CSRA Form 590c Retail Pharmacy Verification Checklist**

▶ Decision

- Cease distribution of CS/LC
- Customer Sign applicable agreement



Education and Training

- ▶ All appropriate ABC associates will be trained on ABC's Diversion Control Program





Questions?